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| 10/516,519 | 07/25/2005 | Arne Mork | 411-US-PCT | 4458 |

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LUNDBECK RESEARCH USA, INC.
ATTENTION: STEPHEN G. KALINCHAK, LEGAL
215 COLLEGE ROAD
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| EXAMINER | |
|---|---|
| STANDLEY, STEVEN H | |

| ART UNIT | PAPER NUMBER |
|---|---|
| 1649 | |

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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/516,519 | MORK ET AL. | |
| | Examiner | Art Unit | |
| | Steven H. Standley | 1649 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1 and 3-30* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1 and 3-30* are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

***Election/Restrictions***

1. This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.
In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group 1, claim(s) 1, 3-11(in part), and 26-30 (in part) drawn to a use of a composition comprising an SSRI and a Gaba receptor antagonist for treating a disorder responsive to SSRIs.

Group 2, claim(s) 1, 3-11(in part), and 26-30 (in part) drawn to a use of a composition comprising an SSRI and a Gaba receptor antagonist for treatment of eating disorders.

Group 3, claim(s) 1, 3-11(in part), and 26-30 (in part) drawn to a use of a composition comprising an SSRI and a Gaba receptor antagonist for treatment of phobias.

Group 4, claim(s) 1, 3-11(in part), and 26-30 (in part) drawn to a use of a composition comprising an SSRI and a Gaba receptor antagonist for treatment dysthymia.

Group 5, claim(s) 1, 3-11(in part), and 26-30 (in part) drawn to a use of a composition comprising an SSRI and a Gaba receptor antagonist for treatment of PMS.

Group 6, claim(s) 1, 3-11(in part), and 26-30 (in part) drawn to a use of a composition comprising an SSRI and a Gaba receptor antagonist for treatment of cognitive disorders.

Groups 7, claim(s) 1, 3-11(in part), and 26-30 (in part) drawn to a use of a composition comprising an SSRI and a Gaba receptor antagonist for treatment of impulse control disorders.

Groups 8, claim(s) 1, 3-11(in part), and 26-30 (in part) drawn to a use of a composition comprising an SSRI and a Gaba receptor antagonist for treatment of attention deficit disorders.

Groups 9, claim(s) 1, 3-11(in part), and 26-30 (in part) drawn to a use of a composition comprising an SSRI and a Gaba receptor antagonist for treatment of drug abuse.

Groups 10, claim(s) 1, 3-11(in part), and 26-30 (in part) drawn to a use of a composition comprising an SSRI and a Gaba receptor antagonist for treatment of depression.

Groups 12, claim(s) 1, 3-11(in part), and 26-30 (in part) drawn to a use of a composition comprising an SSRI and a Gaba receptor antagonist for treatment of anxiety disorders.

Groups 13, claim(s) 1, 3-11(in part), and 26-30 (in part) drawn to a use of a composition comprising an SSRI and a Gaba receptor antagonist for treatment of generalized anxiety disorder.

Groups 14, claim(s) 1, 3-11(in part), and 26-30 (in part) drawn to a use of a composition comprising an SSRI and a Gaba receptor antagonist for treatment of panic disorder.

Groups 15, claim(s) 1, 3-11(in part), and 26-30 (in part) drawn to a use of a composition comprising an SSRI and a Gaba receptor antagonist for treatment of OCD.

Groups 16, claim(s) 1, 3-11(in part), and 26-30 (in part) drawn to a use of a composition comprising an SSRI and a Gaba receptor antagonist for treatment of acute stress disorder.

Groups 17, claim(s) 1, 3-11(in part), and 26-30 (in part) drawn to a use of a composition comprising an SSRI and a Gaba receptor antagonist for treatment of PTSD.

Groups 18, claim(s) 1, 3-11(in part), and 26-30 (in part) drawn to a use of a composition comprising an SSRI and a Gaba receptor antagonist for treatment of social anxiety disorder.

Groups 19, claim(s) 1, 3-11(in part), and 26-30 (in part) drawn to a use of a composition comprising an SSRI and a Gaba receptor antagonist for treatment of bulimia.

Groups 20, claim(s) 1, 3-11(in part), and 26-30 (in part) drawn to a use of a composition comprising an SSRI and a Gaba receptor antagonist for treatment of anorexia.

Groups 21, claim(s) 1, 3-11(in part), and 26-30 (in part) drawn to a use of a composition comprising an SSRI and a Gaba receptor antagonist for treatment of obesity.

Groups 22, Claims 12-21 as it relates to a pharmaceutical composition.

Groups 23, Claims 22-24 (in part) as it relates to a method of identifying compounds useful in treating depression.

Groups 24, Claims 22-24 (in part) as it relates to a method of identifying compounds useful in treating anxiety disorder.

Groups 25, Claims 22-24 (in part) as it relates to a method of identifying compounds useful in treating generalized anxiety disorder.

Groups 26, Claims 22-24 (in part) as it relates to a method of identifying compounds useful in treating panic anxiety.

Groups 27, Claims 22-24 (in part) as it relates to a method of identifying compounds useful in treating OCD.

Groups 28, Claims 22-24 (in part) as it relates to a method of identifying compounds useful in treating acute stress disorder.

Groups 29, Claims 22-24 (in part) as it relates to a method of identifying compounds useful in treating PTSD.

Groups 30, Claims 22-24 (in part) as it relates to a method of identifying compounds useful in treating social anxiety disorder.

Groups 31, Claims 22-24 (in part) as it relates to a method of identifying compounds useful in treating bulimia.

Groups 32, Claims 22-24 (in part) as it relates to a method of identifying compounds useful in treating anorexia.

Groups 33, Claims 22-24 (in part) as it relates to a method of identifying compounds useful in treating obesity.

Groups 34, Claims 22-24 (in part) as it relates to a method of identifying compounds useful in treating phobias.

Groups 35, Claims 22-24 (in part) as it relates to a method of identifying compounds useful in treating dysthymia.

Groups 36, Claims 22-24 (in part) as it relates to a method of identifying compounds useful in treating PMS.

Groups 37, Claims 22-24 (in part) as it relates to a method of identifying compounds useful in treating cognitive disorders.

Groups 38, Claims 22-24 (in part) as it relates to a method of identifying compounds useful in treating impulse control disorders.

Groups 39, Claims 22-24 (in part) as it relates to a method of identifying compounds useful in treating attention deficit disorders.

Groups 40, Claims 22-24 (in part) as it relates to a method of identifying compounds useful in treating drug abuse.

Groups 41, Claims 22-24 (in part) as it relates to a method of identifying compounds useful in treating any other SSRI-responsive disorder.

Groups 42, Claim 25 as it relates to a compound identified by the methods of identifying compounds.

2. This PCT rule defines special technical features as technical features that identify a contribution which each of the claimed inventions, considered as a whole, makes over prior art. The inventions listed as Groups I-55 do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: Khisti et al (2000) disclose the use of fluoxetine (an SSRI) and Bicuculline (a GABA antagonist) as effective in a mouse model of depression. See Table 3 on page 140, wherein fluoxetine and bicuculline are co-administered and exhibit a decrease in immobility time compared to vehicle-only. Thus, Khisti et al disclose that the combination, although not the most effective, was indeed effective at reducing immobility time, which correllated with a decrease in depressive symptoms. Therefor Khisti et al. administer the combination and treat depression. Therefore claim 1-11 lack a special technical feature in common with claims 12-30 and cannot share one with the other claims.

***Requirement for further Restriction Within Groups 1-2***

3. Groups I-2 are drawn to various treatments using a different SSRIs and different GABA receptor antagonists. For prosecution on the merits, further restriction is required. Applicant must elect a single SSRI from the following list:

citalopram, escitalopram, fluoxetine, sertraline, paroxetine, fluvoxamine, venlafaxine, dapoxetine, duloxetine, vilazodone, nefazodone, imipramin, femoxetine and clomipramine.

And corresponding GABA antagonists:

CGP-71982, CGP-76290, CGP-76291, CGP-35348, CGP-36742, CGP-46381, CGP-52432, CGP-54626,CGP-55845,CGP-55845, CGP-62349, SCH 50911, GAS-360, Phaclofen, Saclofen or 2-hydroxysaclofen.

The above-listed drugs are each unique chemical structures with different physical and biological properties. Therefor they do not share a special technical feature with one another. Applicant is advised to elect an SSRI and a GABA antagonist.

***Applicant is advised that the above-listed requirements for further restriction are not species elections.***

4. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

5. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to

final rejection or allowance, whichever is earlier. Amendments submitted after final rejection is governed by 37 CFR 1.116; amendments submitted after allowance is governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

## *Conclusion*

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Steven Standley whose telephone number is **(571) 272-3432**. The examiner can normally be reached on Monday through Friday, 8:00 AM to 5:00 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffery Stucker can be reached on **(571) 272-0911**.

The fax number for the organization where this application or proceeding is assigned is **(571) 273-8300**.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see **http://pair-direct.uspto.gov**. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at **866-217-9197** (toll-free).

Steve Standley, Ph.D.
1/02/07

David Romeo
DAVID S. ROMEO
PRIMARY EXAMINER